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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/643,314 | 08/19/2003 | Rasappa G. Arumugham | ACY33317-D1 | 3547 |

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WYETH
PATENT LAW GROUP
FIVE GIRALDA FARMS
MADISON, NJ 07940

EXAMINER

DEVI, SARVAMANGALA J N

| | |
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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,314

Applicant(s)

ARUMUGHAM ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 4 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Restriction

- 1) Claims 1-18 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 571-272-0531. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 through 13, drawn to an antigenic conjugate and a vaccine composition comprising the same, classified in class 424, subclass 250.1.
 - II. Claims 14 through 18, drawn to a method of immunizing an individual and a method of preventing sepsis in a mammal, classified in class 514, subclass 898.
- 4) Inventions I and II are distinct from one another. Inventions I and II are related as a product and process of use of the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the process of invention II can be practiced with another materially different product such as specific antisera or specific monoclonal antibodies. The conjugate of invention I can be used in a materially different process, for example, an *in vitro* diagnostic assay as a source of coating antigenic reagent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, restriction for examination purposes as indicated above is proper.
- 5) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).
- 6) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

7) This application contains claims directed to more than one species of the generic invention.

(a) Claim 4 recites a plurality of structurally distinct carrier protein species: tetanus toxin or toxoid; diphtheria toxin, toxoid or mutant of diphtheria toxin ClkMI97; *Pseudomonas* exotoxin A; cholera toxin or toxoid; Group A streptococcal toxins; pneumolysin of *Streptococcus pneumoniae*; filamentous haemagglutinin (FHA); FHA fragments of *Bordetella pertussis*; pili or pilins of *Neisseria gonorrhoeae*; pili or pilins of *Neisseria meningitidis*; outer membrane proteins of *Neisseria meningitidis*; outer membrane proteins of *Neisseria gonorrhoeae*; C5A peptidase of *Streptococcus*; or surface protein of *Moraxella catarrhalis*.

(b) Claim 6 recites a plurality of disclosed structurally and genetically distinct gram negative bacterial species: *Neisseria meningitidis*; *Neisseria gonorrhoeae*; *Haemophilus influenzae* non-typeable or *Haemophilus influenzae*; *Haemophilus ducreyi*; *Helicobacter pylori*; *Escherichia coli*; *Chlamydia*; *Salmonella*, *Salmonella typhimurium*, or *Salmonella minnesota*; *Proteus mirabilis*; *Pseudomonas aeruginosa*; *Moraxella catarrhalis*; *Bordetella pertussis*; *Shigella*; *Klebsiella*; or *Vibrio cholerae*.

8) Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. Any argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record, showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C § 103(a) of the other invention.

9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989.

10) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the

Serial Number 10/643,314
Art Unit: 1645

Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: S. DEVI, Ph.D.

ART UNIT: 1645

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 308-4315

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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